MONTANA STATE UNIVERSITY
Research Integrity & Compliance

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Biosafety and Biohazards Noncompliance Policy

Research and Activity Requiring IBC Oversight

University policies and federal regulations require that all research involving biohazardous materials have oversight by the Montana State University (MSU) Institutional Biosafety Committee (IBC). IBC oversight includes research, teaching and diagnostic activities that involve biohazardous material. The IBC defines biohazardous materials as having the potential to cause disease in humans, animals, or plants, or have significant negative environmental or agricultural impact. Biohazardous materials include, but are not limited to, recombinant/synthetic nucleic acids, genetically modified organisms, pathogenic organisms (e.g., human, animal, plant), biological toxins, human or non-human primate materials, and animals or vectors known or suspected to be reservoirs of infectious agents. Research activities requiring IBC approval are outlined in the MSU IBC Manual.

Reporting Suspected Noncompliance

MSU is committed to operating with integrity and in full compliance with all university policies, state laws, and federal regulations. Suspected noncompliance violations may be reported by Principal Investigators (PI), laboratory staff, support staff, or the general public. MSU provides a number of avenues to individuals reporting a suspected noncompliance violation involving biological related activities. Suspected noncompliance may be reported to one's supervisor, Human Resources, IBC Chair, Biosafety Officer, Associate Vice President of Research Integrity & Compliance, or the Vice President for Research and Economic Development. Alternatively, suspected noncompliance may be anonymously reported to an independent contractor, EthicsPoint, 855-753-0486. All concerns will be treated as suspected noncompliance when initially reported, will be treated as confidential to protect all parties involved and will be investigated promptly. MSU will not tolerate retaliation against individuals who report suspected noncompliance violations in good faith.

Examples of Noncompliance

Noncompliance with University policies or federal regulations can be classified as serious or moderate. Serious violations are the result of willful and malicious violations of safety practices, federal regulations, or violations that pose a real or potential threat to individuals, the University, or the environment.
Moderate violations include violations where university policies were unclear and do not pose a threat to individuals, the University, or the environment.
Examples of violations include:

- Failure to acquire the appropriate export, import, or collection permits for applicable research activities.
- Failure to obtain IBC approval prior to initiating research that utilizes biohazardous materials or to

deviate from methods and procedures of an approved IBC protocol prior to approval (e.g., addition of biohazardous materials or procedures that increase the risks of the research).

- Failure to report any significant problems and/or violations of the NIH Guidelines, Select Agent Regulations, Federal and State regulations, or MSU policies.
- Failure to report work-related accidents/exposures and illnesses to Safety and Risk Management.
- Failure to comply with International Air Transport Association (IATA) and/or Department of Transportation (DOT) shipping or transport requirements for infectious substances.
- Failure to instruct, train, and document training of personnel in the procedures and techniques consistent with safety practices and procedures for dealing with reporting accidents.
- Instances demonstrating that biohazardous material was not appropriately contained, inactivated, or disposed of properly.
- Failure to demonstrate and document the correction of work errors and conditions that may have resulted in the release of biohazardous materials.
- Failure to correct deficiencies noted during biosafety inspections within the requested time frame (e.g., within 30 days).

Investigation of Suspected Noncompliance

Promptly after receiving a suspected noncompliance report, the Research Integrity & Compliance (RIC) will initiate an investigation to gather facts to allow determination of the nature and extent of the concern, whether individuals are in immediate risk, and if the concern involves noncompliance with University policy or federal regulations. The involved individual(s) will be informed by the IBC Chair of the noncompliance investigation that is being conducted by the RIC. A subcommittee may be appointed to conduct the investigation. The following considerations are evaluated during the investigation of the suspected noncompliance:

- Whether the reported actions resulted in potential harm to the involved personnel.
- Whether humans, animals, or plants were at risk of harm by the noncompliance.
- Whether a significant negative environmental or agricultural impact has occurred or has the potential to occur.
- Whether the reported violations constitute serious or continuing noncompliance with University policies or federal regulations.

When the investigation deems that noncompliance has occurred with University policies or federal regulations, or that there is a past, present, or future threat to biosafety, the investigator(s) will provide a report to the IBC and the Vice President for Research and Economic Development. The report shall include:

- A description of the noncompliance violation and whether the violation resulted in any adverse events.
- A summary of the records and evidence reviewed during the investigation.
- Identification of University policies or federal violations under which noncompliance occurred.
- Corrective actions that will be implemented to avoid noncompliance in the future and an appropriate date by which the corrective actions will be implemented.

Formal Determination of Noncompliance

When the Biosafety Officer and IBC chair determine that a violation of university policies or federal regulations has occurred, the IBC Chair will notify the involved individual(s) in writing of the noncompliance violation and the corrective actions. In cases where the noncompliance is ongoing and represents a safety issue, the IBC can suspend the research activity. If corrective actions are required, the individual(s) will have a timeline in which the corrective actions must be implemented. The individual(s) will have the opportunity to work with the IBC, the Biosafety Officer, and the IBC Chair to modify the corrective actions if deemed appropriate by the IBC. The Office of the Provost, the PI's Department Head, College Dean, and the Office of Sponsored Programs may be notified of the noncompliance violation.

Examples of Corrective Actions After Determination of Noncompliance

Most moderate noncompliance violations that are not a result of willful or malicious intent of safety practices, federal regulations, or that do not pose a safety threat to individuals, the University, or the environment can be resolved administratively. For serious noncompliance violations the IBC may mandate remedial corrective actions. Such corrective actions may include, but are not limited to:

- Requiring specific training or retraining for involved individuals.
- Additional monitoring by the IBC, Biosafety Officer, or delegated individuals of research activities that pertain to the noncompliance violation.
- Requiring submission and approval of a modification to an already approved IBC protocol prior to continuation of the research for which noncompliance was reported.
- Restricting or limiting the scope of activities that the individual(s) may engage in.
- Suspending approval or terminating an approved IBC protocol.

Procedures for Suspending Research

If at any time during the investigation it is determine that either university policies or federal regulations have been violated, which pose a threat to individuals, the university, or the environment, the Biosafety Officer in consultation with the IBC have the authority to suspend the activity, and to take control of any biohazardous materials present in the facility or laboratory. The decision to suspend an activity will require IBC deliberation and vote. Such deliberation by the IBC may involve the review the available evidence, possible consequences, and interview the individual(s) under investigation. The IBC may determine to not permit research to continue until the appropriate corrective actions have been instituted. The Vice President for Research and Economic Development may stop research in a number of ways, including but not limited to:

- Taking control of research space (i.e., locking laboratory doors)
- Taking control of research animals

Corrective actions required before research activities may resume include, but are not limited to the following:

- Changes in procedures used in research to mitigate the risks.
- Request for documentation of the applicable permits have been granted for the activity.
- Training or retraining of individuals conducting research.
- Request of review and approval of an IBC protocol.

In extreme cases, the IBC may determine that a serious noncompliant violation poses such a risk that the activity is indefinitely suspended, vote to revoke an approved IBC protocol, or subsequently refer the matter to the Vice President for Research and Economic Development for consultation and resolution.